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510(k) SUMMARY

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Device: R. R. P. S. Radius Reconstruction Plating System

Proprietary Name: R. R. P. S. Radius Reconstruction Plating System

Common Name: Small Bone Plating System

Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation
Appliances and Accessories 888.3030

Proposed Regulatory Class: Class II

Device Product Code: 87HRS

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The R. R. P. S. Radius Reconstruction Plating System is a series of titanium plates and screws with plates of T configurations and varying lengths. The system is intended for use in internal fixation of small bones--primarily the distal radius in the forearm. These plates are attached to bone using 2.7 mm diameter titanium bone. All screws are fully threaded and self-tapping with cross-slotted heads.

The substantial equivalence of these devices is based on equivalence in intended use, design, materials and operating principles to several legally marketed devices including the Alta® Modular Trauma Small Bone Plating System (Howmedica Inc.) and the Synthes® Small Fragment and Mini Set (Synthes USA).